Should California Take a More Active Role in the Assessment, Monitoring and Oversight of Biotechnology?

Introduction

With an upcoming major international conference on agricultural biotechnology to take place in Sacramento on June 23-25, 2003, and ongoing legislative interest in these issues, the Senate Office of Research is publishing this issue brief on the role of the state government in the assessment, monitoring and oversight of biotechnology. It is hoped that some of the points made here will help frame the Legislature's deliberations on this important issue.

In 2000, Senate Resolution 34 (Hayden) asked the Senate Office of Research (SOR) to conduct a review of the state agencies that conceivably within their missions could have oversight of the developing biotechnology industry, which combines data and techniques from engineering and technology to address issues in living organisms.

Pursuant to SR 34, SOR, in January 2002, prepared an overview of state and federal regulation of biotechnology, a history of California state government's involvement in biotechnology issues from the 1980s onward, and a survey of the relevant California agencies that could have oversight functions related to biotechnology.

While SOR's focus in the earlier document has been state oversight and monitoring of biotechnology, recent studies of federal biotechnology oversight, particularly with respect to post-market regulation, provide further impetus for state policymakers to examine these issues.

Mostly Biotechnology is Monitored at the Federal Level

One of the findings of Senate Resolution 34 was that state agencies have virtually no resources allocated to evaluating any potential adverse effects of biotechnology on the environment, public health or consumers. SOR's assessment of state oversight indicated this to be true. Biotechnology research choices, laboratory construction, practices, testing procedures, manufacturing practices and marketing of new products are regulated by federal agencies, primarily the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services, along with the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA). *With few exceptions,*

states rely solely upon the federal government for regulation of biotechnology products.

One exception in which California appeared to be moving ahead of the federal government was in the area of cloning. In 1997, California adopted a five-year ban on human-reproductive cloning. The legislation, SB 1344 (Johnston), required the appointment of an expert panel to provide advice to the governor and Legislature about how to proceed when the five years ended. In a January 11, 2002 report, the California Advisory Committee on Human Cloning, established by companion measure SCR 39 (Johnston), unanimously agreed that California should ban human cloning. The Advisory Committee also unanimously agreed that California should not prohibit, but should reasonably regulate, non-reproductive cloning, both public and private. It called for the creation of appropriate institutional review boards to approve permits for any research on non-reproductive cloning. Subsequently, in 2002, SB 1230 (Alpert) passed and was signed into law to extend the ban on human reproductive cloning indefinitely. It also required the state Department of Health Services to establish a committee that would include bioethicists to advise the Legislature and governor on human cloning and other issues related to human biotechnology. In addition, SB 253 (Ortiz) declared it to be the policy of the state to allow human embryonic stem cell research that could result in new medical cures. SCR 55 (Ortiz) of 2002 created a panel to advise the Legislature on stem cell research.

With this key exception, SOR's survey found that the general policy of state agencies with regard to oversight of biotechnology has been to defer to the regulatory branches of the federal government. Some agencies do monitor federal regulatory developments and there are discussions in some of the agencies on increasing the level of monitoring. The California Department of Pesticide Regulation stated that it regularly monitors federal developments in biotechnology, while the state Department of Food and Agriculture reported it reviews and provides input primarily on permits for transgenic (genetically modified) crops.

Underlining the degree to which the state plays a minimal role in the evaluation of the potential health or environmental hazards of biotechnology is the letter from the director of the state Office of Environmental Health Hazard Assessment (OEHHA) to Senator Byron Sher. In 2000, Senator Sher asked the OEHHA to report on its efforts to assess the health hazards and environmental risks from genetically modified organisms. Joan Denton, the director of the office, replied:

> "With reference to your specific questions, we are not aware of any state agency that has specifically interpreted those mandates to evaluate or track the potential human health or environmental hazards associated with the development, manufacture, use or

consumption of genetically modified plants or foods. OEHHA has no specific oversight authority to ensure the safety of genetically modified foods, has not carried out any special investigations or environmental assessments of potential associated health or environmental hazards, and we have not developed health exposure standards for genetically modified organisms."[1]

Additional Studies Confirm Findings of SR 34 and SOR Review

Two studies in 2002 came to the same conclusion as SOR's review and the findings of Senate Resolution 34.

The California Council on Science and Technology in its study, *Benefits and Risks of Food Biotechnology,* July 2002, stated that:

> "In 1985, the Interagency Task Force on Biotechnology, appointed by Governor Deukmejian, was formed to review state and federal regulations regarding new biotechnology. The task force recommended that no special state regulations were justified for genetically engineered products."
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> "In 1994, a task force subcommittee recommended against specific labeling for foods developed using biotechnology. Thus, food derived from genetically engineered sources is regulated in California under the same rules that govern conventional food industries. Some state agencies do request and review technical information regarding genetic modifications for research and experimental use permits."[2]

In October 2002, the California Research Bureau published a study on the biotechnology industry, *California's Bioscience Industries: Overview and Policy Issues.* Citing an April 2000 report by the Legislative Analyst Office to the Senate Budget and Fiscal Review Committee, the report concluded, "The regulation of health, safety and environmental issues relating to biotechnology occurs mainly at the federal level. No state agency is explicitly responsible for evaluating or tracking the effects on human health or the environment associated with transgenic organisms."[3]

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[1] Letter from Joan E. Denton, Director, Office of Environmental Health Hazard Assessment, to Senator Byron Sher, January 20, 2000.

[2] California Council on Science and Technology, *Benefits and Risks of Food Biotechnology*, July 2002, p. 16.

[3] Pollak, Daniel, *California's Bioscience Industries: Overview and Policy Issues,* California Research Bureau, October 2002, p. 69. See also the citation for the Legislative Analyst's Office in the "For Further Reference" section at the end of this paper.

Survey Results

Senate Resolution 34 also asked SOR to "include information from representatives of the biotechnology industry, independent researchers, health and environmental experts, public interest groups, economic analysts and parties with experience in environmental ethics, as well as input from the general public."

This was done in two ways. First, SOR monitored a Food Biotechnology Task Force created in 2000 by SB 2065 (Costa) and its advisory group, which included representation from industry, scientists, researchers and public interest groups. Two published products resulted from the work of this task force, the aforementioned California Council on Science and Technology study and a report to the Legislature by Nuffer, Smith and Tucker, publishers of *Food Foresight,* a trends analysis newsletter on agricultural and food issues. Neither of these studies explicitly addressed the issue of whether more state oversight and monitoring of biotechnology was advisable.

The advisory committee created by the Costa legislation met only once and its primary input was to offer suggestions for the California Council of Science and Technology report. While this panel was made up of individuals with strong and differing viewpoints on the role of the state in the monitoring and oversight of biotechnology, these issues were never aired in public by the panel.

Among the questions that the Legislature might pursue is how this advisory panel should best be administered to ensure balance, sufficient time and opportunity for deliberation, and to be independent. The Advisory Committee of the Food Biotechnology Task Force was chosen very carefully to ensure balanced representation from industry representatives, farmers and ranchers, scientists, researchers, environmentalists, public interest groups, organic farmers etc., but the group met only once and never deliberated these issues in depth. The Task Force met the requirements of the legislation by describing the existing federal and state regulatory structure but did not delve further to ask whether this was sufficient. The Food Biotechnology Task Force was administered by three state agencies, two of who's primary focus is the promotion of the industry, the Department of Food and Agriculture (CDFA) and Technology, Trade and Commerce, although CDFA is also mandated with the protection of the public health, safety, and welfare.

SOR also undertook an independent survey of organizations, companies, associations, and individuals that have a stake or interest in biotechnology regulation. This survey was conducted by SOR with the assistance of Leah Cartabruno.

We found that genetic modification caused the greatest controversy and concern in its agricultural and industrial applications, rather than in human health care. These controversies were what respondents in the Cartabruno survey focused on. Responses ranged from those who advocated a total ban on genetically modified crops to those who felt that no state oversight was warranted. In between were advocates of a moratorium on genetically modified crops and those who suggested tighter licensing rules and state oversight.

One of the major points made by Greenpeace, an advocate for a ban on food biotechnology, is that

> "It may be impossible to do long-term environmental safety testing of genetically engineered agriculture. Like any other potentially invasive species, GE crops have never evolved in the environments into which they are introduced. The effect of newly introduced genes under real world conditions, in different climates or in reaction to different pests or diseases, is completely unpredictable, posing a threat not only to the crop, but also to related species and the ecosystem."

On the other side of this issue are organizations such as the California Farm Bureau, which stated

> "This is a federal issue. The state has a role in monitoring what types of GMO crops are grown but not in regulating them. If California has distinct requirements, it will make it difficult for this technology to progress effectively and safely."

The Consumers Union, arguing for increased state regulation, stated

> "Since the FDA does not require human safety testing, just voluntary safety consultations, we feel California should have more rigorous standards. Just as Cal EPA's pesticide law is more stringent than the federal law, we feel California should require appropriate testing of GMOs. "

Issue: Are Federal Regulations Adequate? Is There a Need for a State Role?

It is clear, as recent legislative debates on transgenic fish and stem cell research have shown, that genetic modification will continue as a subject of public concern and controversy, although there also is wide support for the life-enhancing benefits it has brought to medical advancements in health care.

Applications of these emerging technologies, which combine the life sciences with human and animal engineering in new and sometimes unforeseen ways,

raise many moral, ethical, health and environmental questions. It is possible we do not fully understand the long-term consequences of their use. In this context, it is difficult to determine whether the most appropriate forum for regulation and oversight of biotechnology should remain with the federal government, as scientific developments and health-care advances continue to play out on a national front.

In addition, two recent studies published by the National Academy of Sciences[4] and the Pew Initiative on Food Biotechnology[5] have raised serious issues about the adequacy of federal regulation of food biotechnology, particularly with regard to products that have already entered the market and to future technological developments in the industry. The StarLink incident in which genetically modified corn hybrids, restricted for animal feed and industrial use only, found their way into the human food supply, raising questions about the adequacy of the regulatory system to oversee biotech products after they have entered the market. The StarLink incident did have the result of adding some impetus to the passage of the California Rice Certification Act of 2000 (AB 2622 Dickerson). The bill was backed by the California Rice Commission, representing growers and millers who were worried about the potential loss of export markets if GMO rice was accidentally mixed in an overseas shipment.

In the Food Biotechnology Task Force Report prepared by Food Foresight in January 2003 to the Legislature, it is noted that

> "A reccurring theme in collecting data for this report suggests inadequate GE regulatory systems to ensure human health and environmental safety." [6]

The authors go on to say

> "California, like most states, follows federal oversight of biotechnology in lieu of specific state regulations on the issue. Food derived from GE sources is regulated under the same rules that govern conventional food. Some state agencies do request and review technical information regarding genetic engineering for research and experimental use permits. The state requires no special labeling, special permits, technical review of genetic engineering production methods or any special

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[4] National Research Council, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, 2002.

[5] Michael R. Taylor and Jody S. Tick, *Post-Market Oversight of Biotech Foods: Is the System Prepared?,* April 2003, www.pewagbiotech.org.

[6] Food Biotechnology Task Force, *A Food Foresight Analysis of Agricultural Biotechnology: Report to the Legislature,* January 1, 2003, p. 14

> tracking of movement, sale or planted acreage. With the potential for more state regulatory involvement, it will be imperative that adequate laboratory capacity is available." [7]

In 2001, 22 governors signed 22 state bills regarding food biotechnology. In addition, 11 states introduced labeling measures to identify foods containing any ingredient from a GE crop. Concerns have been raised that states enacting biotechnology legislation could result in a national patchwork of laws that vary from state to state.[8] Issues have also been raised that state restrictions on GMO crops could result in restricting interstate commerce. However, with regard to pesticides, the industry insists on a role for a state-based department. Since it is appropriate for California to have more stringent air quality and pesticide standards than the federal government, should the state commit more resources to assess any possible adverse effects on the environment, health and consumers from this relatively new industry?

As should be clear from this paper, the appropriate role of the state in the monitoring and oversight of biotechnology has yet to be clearly defined or determined. However there should be no doubt that a role for the state is an appropriate avenue of study.

The Human Cloning Advisory Committee was an example of a task force on a similarly controversial issue that was able to come to consensus recommendations on how the state should proceed with regard to that issue. This panel grew out of forum/roundtables and hearings held by the Senate Select Committee on Genetics, Genetic Technologies and Public Policy. As the panel was deliberating on the issue the committee in 1999 held a lecture series which included "Human Cloning: To Legislate or Not" as one of its topics. The panel was established by the Department of Health Services and funding came out of existing funds of that department.

Given the fact that the Food Biotechnology Task Force did not address the issue of the whether or not the existing regulatory structure is sufficient, it is the recommendation of this paper that the Legislature establish an advisory body such as the California Advisory Committee on Human Cloning with the charge of reporting to the Legislature on the potential impacts to human health and the environment from biotechnology and to make recommendations to the Legislature on whether greater resources of the state should be dedicated to monitoring and oversight of biotechnology, particularly food biotechnology and transgenic species such as fish. The Legislature may want to consider creating the panel itself or a select committee to oversee the process.

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[7] *Food Foresight Analysis,* p. 14
[8] *Food Foresight Analysis* p. 17

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